

Amendments to the Specification:

Please replace the paragraph beginning at page 3, line 6, with the following rewritten paragraph:

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-- Sensors should have high selectivity and sensitivity, have rapid recovery times with no hysteresis, long lifetimes if not single use, low drift, automated calibration, self-diagnostic, low cost, no reagent additions required and no sample preparation. It is obvious that presently available chemical sensors and biosensors do not meet these criteria (World Biosensor Market, Frost and Sullivan, Report 5326-32, 1997). National Institute of Standards and Technology, *Nano-and MEMS Technologies for Chemical Biosensors* (A231 Administration Building, Gaithersburg, MD 20899) found at www.atp.nist.gov/atp/focus/98wp-nan.htm. --

-- Please replace the paragraphs beginning at page 13, line 1, with the following rewritten paragraph:

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-- The particular means for detecting a change in the inventive sensor and/or the particular means for activating a change in the inventive sensor is generally not considered part of the present invention. For example, it is known that ultrasound energy may be employed to generate both one-way and two-way shape memory effects in nickel-titanium alloys. V.V. Klubovich, V.V. Rubanick, V.G. Dorodeiko, V.A. Likhachov, and V.V. Rubanick Jr. (Institute of Tech. Acoustics, 13 Ludnikova, 210026 Vitebsk, Belarus,) *Generation of Shape Memory Effect in Ti-Ni Alloy by means for Ultrasound*, Abstract 1.P12, SMST-97 conference found at www.fwsystems.com/professional/smsstabs.html. Using ultrasound energy to non-invasively induce stent heating has also been confirmed by B. Lal, et al. in their abstract entitled *Non-Invasive Ultrasound Induced Heating of Stents: Importance of Stent Composition*, which may be found at URL <http://www.hotplaque.com/frames/abstracts/rabs6.htm> and URL <http://ex2.excerptamedica.com/00acc/abstracts/abs1065-117.html>. Lal, et al. hypothesized that gentle heating can be accomplished using ultrasound (US) and a constant temperature can be maintained using pulsed US. The heating rate of an object under the same US power and frequency is determined primarily by its absorption and

reflection rates. To test their hypothesis, they used a phantom of 5.08 cm thick layer of pork muscle, in which various annular stent shape materials were placed. To monitor the heating multiple hypodermic thermocouples were used. The heating was induced using FDA-approved levels of therapeutic ultrasound (intensity 0.5-2.5 W/cm², frequency 1-3 MHz) in both pulse and continuous modes. It was found that nylon, and some types of PVC, exhibit temperature increases that are larger (2-35° C) and faster (1.5-15 times) than the surrounding tissue, while Lexan, PTFE, Latex, Teflon, Ceramic and Delrina do not display selective heating. A modest heating effect (2° C increase in 15 minutes) was also found in a metal stent. Lal, et al. concluded that ultrasound heating of tissue adjacent to a prosthesis depends on stent composition, induction of thermal apoptosis by ultrasound may prove to be effective in limiting restenosis in polymeric stents and grafts. Issues that need to be addressed include the optimal biocompatible material and design of stents and the *in vivo* effects of phased-array US on the stented artery and its surrounding tissues. Lal, et al. believed that by using fast-heating, non-toxic materials, ultrasound-heated stents could be devised. --

Please replace the paragraphs beginning at page 13, line ²⁹ 4, with the following rewritten paragraph:

-- Similarly, microwave radiation may be used to generate shape memory effects in shape memory alloys. It is known, for example, that microwave radiation may be used for stent diathermy in stainless steel stents. S. Naguib, *et al.* in *Stent diathermy using focused ultrasound & microwave* found at www.hotplaque.com/frames/abstracts/rabs3.htm sought to use ultrasound and microwave energy to non-invasively heat the stent and its surrounding plaque. Using Palmaz-Schatz stents as well as several stent-shape biopolymer materials embedded inside the phantom, Naguib, *et al.* continuously mapped rise in temperatures in the system upon ultrasound and microwave irradiations in separate settings. Temperature monitoring was done using a 12-channel ultrathermometer (0.01°C) with thermocouples (ultrasound) and fiber optic sensors (microwave). Therapeutic ultrasound at the frequency of 1-3 MHz and intensity of 0.5-2.5W/CM² was used. Microwave radiofrequency was delivered by an antenna using a frequency of 2.45 GHz and a power of 5.37 & 10.22 watts. In their ultrasound

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experiment Naguib, *et al.* found that the temperature of outer surface of stent and its surrounding tissue increased significantly higher than other sites. The rise in temperature varies by the type of biopolymer where silicon stent heated faster and more than polyurethane and polytetrafluoroethylene. Similar results were observed in the microwave experiments. Infrared thermography was used to measure the increased temperatures during delivery of both ultrasound and microwave radiation.

Please replace the paragraph beginning at page 14, line 28, with the following rewritten paragraph:

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-- It is well known that metal stents are radiopaque and are detectable under radiographic imaging, such as fluoroscopy. Detection of the inventive sensor device may be accomplished by radiographic imaging, ultrasound imaging (either using frequencies which also generate a shape memory effect or not), magnetic resonance imaging, RF imaging or similar methods. The use of magnetic resonance imaging to image nitinol stents is known in the art. See, *e.g.*, Rahdert, D, Hakim, B., *Magnetic Resonance compatibility of Ni-Ti Stents*, Abstract 8.P1, SMST-97 conference (International Organization on Shape Memory and Superelastic Technologies) found at fwsystems.com/professional/smstabs.html, in which they describe they studied the compatibility of Ni-Ti coronary stents using magnetic imaging to assess a) ferromagnetic forces; and b) artifacts. Two methods were used to measure force: horizontal sliding and pendulum deflection. Ferromagnetic forces were found to be less than 10% of stent weight. Artifacts were assessed to be small. --

Please replace the paragraph beginning at page 14, line 28¹¹, with the following rewritten paragraph:

-- The use of particulate paramagnetic metal iron oxide as a contrast medium to image and model vascular profiles under magnetic resonance imaging (MRI) has been demonstrated by Mitra Rajabi, *et al.* at the University of Texas-Houston, Houston, Texas, United States and the University of Texas-Medical Branch at Galveston, Galveston, Texas, United States. In an abstract published for presentation at the ACC 2001, the

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American College of Cardiology Scientific Session scheduled for March 18-21, 2001, the abstract may be found at www.hotplaque.com/ACC/ACC2001%20abstracts.htm#5, Rajabi, *et al.* describe a technique for imaging plaque inflammation. Super paramagnetic iron oxide (SPIO) particles are magnetic resonance (MR) imaging contrast media that have a central core of iron oxide generally coated by a polysaccharide layer. They shorten the relaxation time, predominantly the T2 relaxation time. Rajabi, *et al.* hypothesized that inflamed vulnerable atherosclerotic plaques would preferentially take up these nano-particles by virtue of macrophage infiltration, leaking vasa vasorum and fissured thin caps. To test their hypothesis, they injected 1- 3 mmol Fe/kg super paramagnetic iron oxide to six Apo E deficient and two C57bl mice through the tail vein, after first obtaining baseline MR imaging. Post-contrast MR imaging were performed in day 5 with the same parameters (TR=2.5, TE=0.012, FOX=6 6, slice thickness=2.0mm, flip angle (orient)=trans, and matrices=256 x 256). The aorta at the level of kidney was selected for comparison of the baseline and post-contrast images. Rajabi, *et al.* found decreased signal intensity in SPIO injected Apo E deficient mice and no decrease in signal intensity in SPIO injected C57bl mice. --

Page 21, line 21, please replace the paragraph starting at line 21 and ending at Page 22, line 23, in its entirety, with the following new paragraph:

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-- We turn now to Figures 5-7B, in which there is illustrated the inventive *in vivo* sensor device 30 in the form of an endoluminal stent adapted for non-invasive vascular modeling and imaging. The inventive *in vivo* sensor device 30 comprises a plurality of structural elements 32, 36, separated by a plurality interstitial openings 34, which serve to define walls of the sensor device 30. The particular geometry of the plurality of structural elements 32, 36 may be selected based upon the intended function of the sensor device 30, e.g., a stent or stent-graft, and is not a significant factor in the present invention. It will be appreciated by those of ordinary skill in the art that alternative geometries of the structural elements 32, 36 other than those depicted in the Figures are contemplated by the present invention. The plurality of structural elements 32, 36 which define the sensor device 30 are fabricated of at least one of a shape memory materials, superelastic materials, plastically deformable materials and/or elastically deformable

materials, such as stainless steel and/or nickel-titanium alloys, that permit the sensor device 30 to expand within an anatomical passageway, for example a blood vessel, at body temperature, *i.e.*, the martensite transition temperature (in the case of a shape memory material) is below, but in proximity to, body temperature. In order to provide sensor functionality and permit vascular imaging and modeling, the inventive sensor 30 further comprises regions of the structural elements 32, 36 which have a second shape memory and/or superelastic material therewith (hereinafter the "second material"), which has, for example, a martensite transition temperature (or σ coefficient) which is higher than that of the base material for the structural elements 32, 36. Having a second material with either a higher transition temperature or a higher σ coefficient, allows for changing device 30 geometry or conformation upon application of internally or externally applied forces. For example, heat energy may be applied by either external microwave transmissions directed from outside the body to the device 30 or by a laser catheter that is used to apply laser energy to the sensor device 30. In either case, localized heating of the sensor device 30 to above the transition temperature of the second material causes the structural elements 32, 36 to undergo martensitic transformation with a concomitant change to the geometry and/or conformation of the sensor device 30. Upon martensitic transformation, at least some of the structural elements 32, 36 will change their positioning relative to the geometry of the sensor 30, as represented by arrows 38 in Figure 6, which is an enlarged view of region 6 in Figure 5, thereby changing the configuration of openings 37 between adjacent pairs of structural elements 32, 36. The sensor 30 in its changed geometry and/or conformation may then be imaged using conventional non-invasive imaging techniques to provide an image of the vascular profile. --